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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,799	06/07/2001	Nagendra Rangavajhyala	112701-194	2978

29157 7590 04/28/2003

BELL, BOYD & LLOYD LLC  
P. O. BOX 1135  
CHICAGO, IL 60690-1135

EXAMINER

PADEN, CAROLYN A

ART UNIT PAPER NUMBER

1761

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	09/681,799		RANGAVAJHYALA ET AL.	
	Examiner		Art Unit	
	Carolyn A Paden		1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 15-25 is/are rejected.
- 7) ☒ Claim(s) 4, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                                    |                                                                             |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2&amp;3</u> . | 6) <input type="checkbox"/> Other:                                          |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10, 20-22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fritsch (EP 1,236,405) and see page 3, lines 27, 28, 35-39, 46-48, example 2 and 3.

Fritsch discloses a hypoallergenic formula that includes soy protein. The soy protein is a hydrolysate with a degree of hydrolysis of less than 25%, preferably of about 10-20% (column 3, paragraph 0023). The product is used in infant formula at example 3. The infant formula includes 3.4% fats, 7% carbohydrates, vitamins, minerals as well as 1.6% peptides. The carbohydrate component includes rice starch and corn starch (page 4, paragraph 0038). No lactose is included in the sample. The product is provided to reduce soy allergenicity. The formula would be expected to provide comfort because it would be easily digestible. The formula has a reduced whole soy protein because it is hydrolyzed.

Claims 9-12 and 15-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Borschel.

Borschel discloses a pediatric formula for infants that includes a stabilizer, vitamins, minerals, carbohydrates, lipids and protein (see abstract). The protein sources include soy protein hydrolysate as a selection (column 5, lines 10-11 of U.S. Patent 6,365,218 and page 3, lines 2-3 of U.S. 2—2/0176911). The protein, fat and carbohydrate content are shown at Table 1 to include the range shown in the claim. Because protein hydrolysate formulas are easily digestible, one would expect that the product would provide comfort.

Claims 4, 13 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is 703-308-3294. The examiner can normally be reached on Monday to Friday from 7am to 3:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-305-7718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

*Carolyn Paden*  
CAROLYN PADEN 4-15-03  
PRIMARY EXAMINER  
GROUP 1360 1761